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10/054,619	01/22/2002	Richard J. Melker	UF-270	5786

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EXAMINER	
NATNITHITHADHA, NAVIN	
ART UNIT	**PAPER NUMBER**
3736	13

DATE MAILED: 06/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/054,619	Applicant(s) MELKER ET AL.	
	Examiner Navin Natnithithadha	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claim 38 is objected to because of the following informalities:

It appears that the claim is meant to state a breath analyzer for analyzing the patient's breath and providing a signal. The Examiner's suggests amending "that provides" with - - and providing - -. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claim 33 is rejected under 35 U.S.C. 102(b) as being anticipated by Brown et al, US 5,303,575 A.

Claim 33: Brown discloses a method for monitoring endogenous compounds (alcohol) found in a patient's blood (blood alcohol content level), comprising: sampling a patient's expired breath (see col. 7, lines 10-17); analyzing the breath for concentration of endogenous compounds using sensor technology (see col. 7, lines 53-56); and calculating the concentration of endogenous compounds in the patient's blood, wherein the endogenous compound is alcohol (see col. 8, lines 56-59 and col. 9, lines 3-12).

3. Claims 33, 34, and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Harte et al, US 3,792,272 A.

Claims 33, 34, and 40: Harte discloses a method for monitoring endogenous compounds found in a patient's blood (see col. 1, lines 14-22), comprising: sampling a patient's expired breath (see col. 7, lines 43-50); analyzing the breath for concentration of endogenous compounds using sensor technology (see col. 8, lines 31-54); and calculating the concentration of endogenous compounds in the patient's blood (see col. 5, lines 15-16 and col. 11, lines 7-8), wherein the endogenous compounds are ketones and acetone (see col. 2, lines 8-15 and lines 27-31, and col. 12, lines 29-31). Column 2, lines 8-31 would also suggest monitoring endogenous compounds such as glucose, electrolytes and ammonia.

4. Claims 35-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Westenskow et al, US 5,094,235 A.

Claim 35: Westenskow discloses an anesthetic agent delivery system for delivering a desired dose of anesthetic agent (nitrous oxide) to a patient, comprising: an anesthetic supply (307) having a controller (302) for controlling the amount of anesthetic agent provided by the supply (see col. 5, lines 46-56); a breath analyzer (106) for analyzing the patient's breath for concentration of at least one substance indicative of the anesthetic agent concentration in the patient's bloodstream that provides a signal to indicate the anesthetic agent concentration delivered to the patient (see col. 7, lines 14-22; and a system controller 5 connected to the anesthetic supply which receives the

signal and controls the amount of anesthetic agent based on the signal (see col. 8, lines 9-14).

Claim 36: Westenskow discloses the breath analyzer comprises a collector 114 (exhale branch), a sensor 106, and a processor 5.

Claim 37: Westenskow discloses a sensor as generally as an anesthetic agent sensor 106, which is capable of having a semiconductor gas sensor technology, conductive polymer gas sensor technology, or surface acoustic wave gas sensor technology.

5. Claim 39 is rejected under 35 U.S.C. 102(b) as being anticipated by Georgieff, US 6,328,708 B1.

Claim 39: Georgieff discloses a method for monitoring perflubron levels in an anemic patient (see col. 10, lines 32-34), comprising: sampling a patient's breath (see col. 9, lines 3-6); analyzing the breath for concentration of perflubron using sensor technology (see col. 9, lines 11-15); and calculating the blood concentration of perflubron based on the concentration (see col. 9, lines 13-14).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

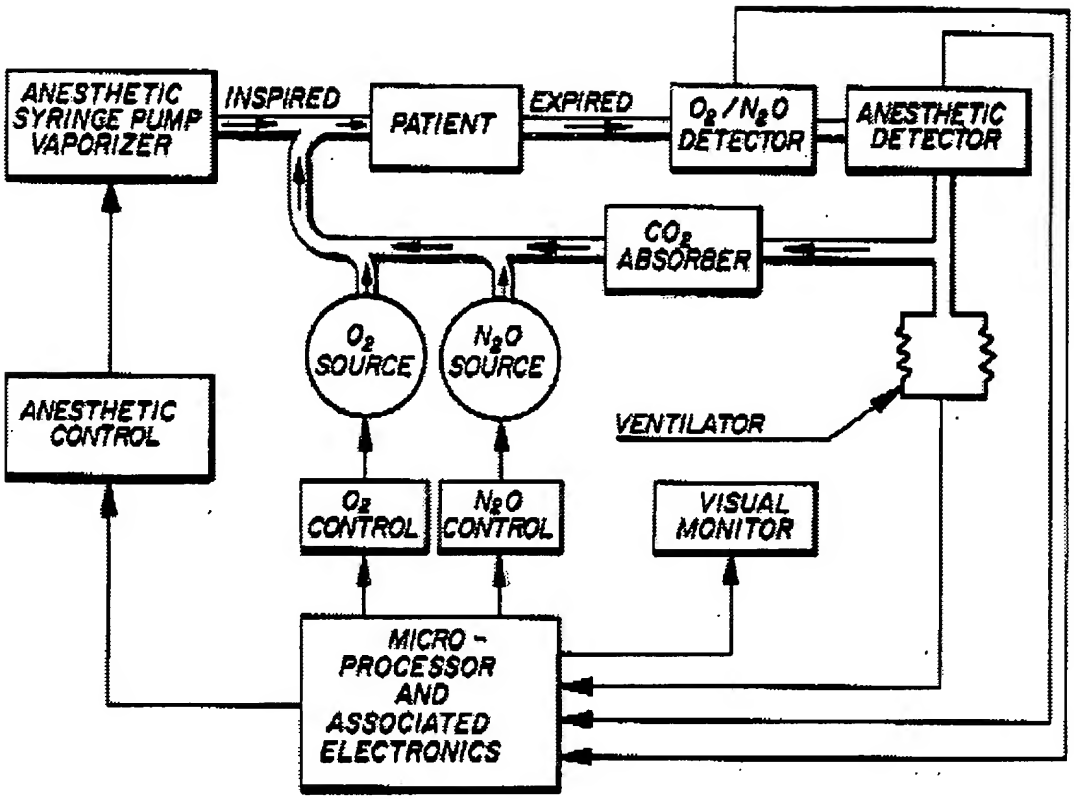
> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claim 2, 3, 9, 18-20, 22, 23, 25, and 27-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jewett et al, US 4,150,670 A, in view of Ueda et al, US 5,573,005 A.

Claim 3: Jewett teaches a method for determining the depth of anesthesia wherein at least one anesthetic agent is administered into a patient's blood stream during the delivery of anesthesia (see fig. 6 below and col. 9, line 65 to col. 10, line 27), comprising: sampling a patient's expired breath (see fig. 6); analyzing the breath for concentration of at least one substance indicative of the anesthetic agent using sensor technology (see col. 10, line 21); determining depth of anesthesia based on the concentration (see col. 9, line 65 to col. 10, line 27).

FIG.6



Jewett does not teach using a flow sensor to detect starting and completion of exhalation during the sampling step. However, Ueda teaches an expiration collection device comprising a flow sensor 20 to detect starting and completion of exhalation (see col. 2, lines 23-35, col. 3, line 13-14, and col. 5, lines 37-54). It would have been obvious to one of ordinary skill in the art to modify Jewett's method to use a flow sensor to detect the start and completion of exhalation in order to an efficient means to collect a constant amount of expiration from a subject for correctly analyzing the expiration gases as suggested by Ueda in column 1, lines 63-67.

Claim 2: It is inherent to the Jewett method that the analyzing of the expired anesthetic agent concentration would be after a predetermined period of time. The claim limitation did not state when the predetermined period of time started. In Jewett's method, analyzing the expired anesthetic agent concentration is capable of occurring during any portion of the sampling of the patient's breath.

Claim 9: Jewett teaches method steps can be repeated periodically to monitor trending over time (see col. 10, lines 55-63).

Claims 18 and 19: Jewett teaches the sampling is continuous (see col. 10, lines 55-56). It is also obvious to one of ordinary skill in the art to modify Jewett's sampling to be periodic instead of continuous as a design choice.

Claims 22 and 23: Jewett teaches recording data and transmitting data resulting from analysis of the patient's breath (see fig. 6).

Claim 25: Ueda teaches capturing the patient's breath in a vessel (syringe) 12prior to analysis (see fig. 1).

Claim 27: Ueda teaches detecting exhalation of the patient's breath with a sensor 20 (see fig. 1).

Claims 28-30: Jewett teaches the substance indicative of the anesthetic agent is free anesthetic agent, metabolites of the anesthetic agent, or both as generally expired anesthetic concentration (see col. 10, lines 21-22).

Claims 31 and 32: Jewett teaches monitoring the expired anesthetic concentration adjusting the administration of the anesthesia (see col. 10, lines 25-27).

7. Claims 4-8, 10-17 21, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jewett et al, US 4,150,670 A, in view of Ueda et al, US 5,573,005 A, and further in view of Struys et al, US 6,599,281 B1.

Claims 4-7: Jewett does teach controlling the delivery of anesthetic agent to a patient (see fig. 6 above and col. 10, lines 23-28). Neither Jewett nor Ueda teach a infusion pump and controlling an infusion pump to deliver an anesthetic agent. However, it is well known in the art to anesthetize a patient using either an infusion pump or by anesthetize gas source. Struys et al, US 6,599,281 teaches anesthetic agent (medication) delivery control device similar to Jewett's invention comprising a infusion pump (see col. 5, lines 61-65) instead of an anesthetize gas source. It is there for obvious to use either an infusion pump or a gas source for anesthesia in combination with Jewett's invention. Struys et al also discloses adjusting the infusion rate, which is capable of being adjusted continuously.

Claim 8 and 10-14: Neither Jewett nor Ueda specifically teach using anesthetic agents comprising Remifentanil, Propofol, agents used for amnesia, analgesia, muscle relaxation, sedation, or use of a combination of agents. Struys teaches a similar method to Jewett's invention using Propofol, muscle relaxants and generally other medications to anesthetize a patient (see col. 1, lines 57-67 and col. 15, lines 55). It is well known in the art that anesthetic agents can encompass the agents listed above and, therefore, it would be obvious for one of ordinary skill in the art to use those agents in combination with Jewett's or Struys's invention in order to properly anesthetize a patient.

Claims 15 and 16: Neither Jewett nor Ueda teach determining anesthetic or analgesic blood concentration. However, Struys teaches a similar method to Jewett's invention including determining the anesthetic agent blood concentration. It would be obvious for one of ordinary skill in the art combine Jewett's with Struys's invention in order to properly anesthetize a patient.

Claim 17: Neither Jewett nor Ueda teach determining a level indicative of recovery. However, Struys teaches a similar method to Jewett's invention including monitoring the condition of a patient through the course of anesthesia, which would include recovery (see col. 5, lines 35-45). It would be obvious for one of ordinary skill in the art combine Jewett's with Struys's invention in order to properly anesthetize a patient.

Claims 21 and 24: Neither Jewett nor Ueda teach comparing the analysis with a predetermined signature profile or the sensor producing a unique electronic fingerprint to characterize the anesthetic concentration. However, Struys teaches using a patient response profile to operate the control of anesthetic delivery (see col. 6, lines 15-29). It would be obvious for one of ordinary skill in the art combine Jewett's with Struys's invention in order to properly anesthetize a patient.

8. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jewett et al, US 4,150,670 A, in view of Ueda et al, US 5,573,005 A, and further in view of Lewis et al, US 6,244,096 B1.

Claim 20: Neither Jewett nor Ueda specifically teach analyzing the patient's breath by sensor technology selected from semiconductor gas sensor technology, conductive

polymer gas sensor technology, or surface acoustic wave gas sensor technology. However, it is well known in the art to use the above sensor technology in monitoring anesthesia. For instance, Lewis discloses monitoring anesthetic agent concentrations using surface acoustic wave gas sensor technology (see col. 7, lines 10-11 and col. 12, line 60 to col. 13, line 12).

9. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jewett et al, US 4,150,670 A, in view of Ueda et al, US 5,573,005 A, and further in view of Psaros et al, US 5,501,212 A.

Claim 26: Neither Jewett nor Ueda teach dehumidifying the patient's breath prior to analyzing. However, it is well known in the art to dehumidifying exhaled breath during monitoring of anesthesia. For instance, Psaros teaches a dehumidifier 8 for expired gas in connection with a anesthesia delivery circuit 2 (see col. 1, lines 16-21 and col. 4, lines 40-49 and 63-67).

10. Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Struys et al, US 6,599,281 B1 in view of Westenskow et al, US 5,094,235 A.

Claim 38: Struys discloses an apparatus for administering intravenous anesthesia (medication) to a patient (see abstract) comprising: at least one supply (infusion pump) of at least one intravenous anesthesia agent (see col. 5, lines 59-63); intravenous delivery means 112 (medication delivery unit) for controllably intravenously delivering at least one intravenous anesthesia agent to the patient (see col. 5, lines 46-58); and a

system controller 108 (medication delivery controller) connected to the intravenous delivery means which receives a signal and controls the amount of anesthetic agent based on the signal (see col. 5, lines 52-58). Struys does not disclose a breath analyzer for analyzing the patient's breath for concentration of at least one substance indicative of the anesthetic agent in the patient's bloodstream that provides a signal to indicate the anesthetic agent concentration delivered to the patient. However, Westenskow discloses an apparatus for administering anesthesia to a patient comprising: a breath analyzer (106) for analyzing the patient's breath for concentration of at least one substance indicative of the anesthetic agent concentration in the patient's bloodstream that provides a signal to indicate the anesthetic agent concentration delivered to the patient (see col. 7, lines 14-22; and a system controller 5 connected to the anesthetic supply which receives the signal and controls the amount of anesthetic agent based on the signal (see col. 8, lines 9-14). It is obvious to one of ordinary skill in the art at the time of the invention was made to modify Struys invention to control medication delivery based on a signal from a breath analyzer in order to provide a more efficient or less intrusive controlled feedback drug delivery system. Since Struys broadly discloses a sensor package 104 (see col. 35-44) to determine the patient's response to a delivered medication, it is the Examiner's position that the sensor package can be a breath sensor for analyzing the patient's breath for concentration of an anesthetic agent and provides a signal to indicate the anesthetic agent concentration delivered to the patient.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Navin Natnithithadha whose telephone number is (703) 305-2445. The examiner can normally be reached on Monday-Friday, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Beth Jones can be reached on (703) 308-3400. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Navin Natnithithadha
Patent Examiner
GAU 3736
June 1, 2004

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ACTING SUPERVISORY PATENT EXAMINER